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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/648,078 | 08/26/2003 | Terry L. Ray | 4042-A4 | 3377 |

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EXAMINER

ALI, SHUMAYA B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,078

Applicant(s)

RAY ET AL.

Examiner

Shumaya B. Ali

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>DETAILED ACTION</u> . |

Art Unit: 3743

DETAILED ACTION

Election/Restrictions

In response to the election/restriction, the Applicant has elected species I, claims 1-4,7-14, and 17-20 without traverse.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1,11, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No.**

6,286,510B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because limitations cited in claims 1,11, and 20 are recited in claims 1 and 14 of the published patent. Further, “an insert” of claims 1 and 14 reads on “body” and “an

Art Unit: 3743

engagement element” reads on “a peripheral anchor” of claims 1,11, and 20 of the currently pending application.

3. Claims 1,11, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,6, and 11 of U.S. Patent No.

6,371,118B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because limitations cited in claims 1, 11, and 20 are recited in claims 1,6, and 11 of the published patent. Further, “an insert” of claims 1, 6, and 11 reads on “body” and “second portion” reads on “peripheral anchor” and “first portion” reads on “seal” of the currently pending application.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-14, and 17- 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington et al. US Patent no. 5,954,715

As to claim 1, Harrington et al. disclose a method and apparatus for tubular occlusion (col2. lines 13-17) see figs. 2b, and 6, wherein the apparatus comprising: a body (30) having a base with a periphery (see fig.2b); body for overlying and engaging uterine tissue leading to the opening and receiving fibroblast in-growth to create a hermetic seal between the oviduct and the uterine cavity; and a seal (38, col.4 lines 39-43) carried by the peripheral anchor (fig.6, 24)

portion extending from the base for securing the body to the uterine tissue leading to the opening, the base overlying the opening.

As to claim 2, Harrington et al. disclose wherein the peripheral anchor portion (**fig.7, 49**) comprises a plurality from the pikes extending periphery of the base.

As to claim 3, Harrington et al. disclose wherein the spikes terminate tissue-engaging structure (**see fig.3b**).

As to claim 4, Harrington et al. disclose wherein the tissue engagement structure includes barbs (**fig.7, 49**).

As to claim 7, Harrington et al. disclose wherein the body supports an engaging member that may be grasp by a tool (**catheter 20, col.2 lines 25-30**) and which allows the apparatus to be manipulated during installation.

As to claim 8, Harrington et al. disclose wherein the engaging member is carried by an extension of the body (**see fig. 3b, 20**).

As to claim 9, Harrington et al. disclose wherein the seal is formed of a biocompatible material that stimulates in-growth of fibroblastic tissue (**col.4 lines 45-55**)

As to claim 10, Harrington et al. disclose wherein the body is fabricated of a biodegradable material (**col.4 lines 45-55**)

As to claim 11, Harrington et al. disclose a method and apparatus for tubular occlusion (**col2. lines 13-17**) **see figs. 2b, and 6**, wherein the apparatus comprising: a body (**30**); a seal (**38, col.4 lines 39-43**) coupled to the body for engaging uterine tissue surrounding and defining the opening, the seal formed of a biocompatible material (**col.4 lines 45-55**) that stimulates in-growth of fibroblastic tissue hermetic seal; and create a continuous a peripheral anchor portion

Art Unit: 3743

supported by the body for engaging the uterine tissue and maintaining the seal in engagement to the uterine tissue surrounding and defining the opening, the seal overlying the opening (see **fig.2b**).

As to claim 12, Harrington et al. disclose wherein the peripheral anchor portion comprises a plurality of spikes (**fig.7, 49**) extending from the periphery the base.

As to claim 13, Harrington et al. disclose wherein the spikes terminate in a tissue engaging structure (see **fig.3b**).

As to claim 14, Harrington et al. disclose wherein the tissue engagement structure includes barbs (**fig.7, 49**). .

As to claim 17, Harrington et al. disclose wherein the body supports an engagement member that may be grasp by a tool (**catheter 20, col.2 lines 25-30**) and which allows the apparatus to be manipulated during installation

As to claim 18, Harrington et al. disclose wherein the engagement member is carried by an extension body (see **fig. 3b, 20**).

As to claim 19, Harrington et al. disclose wherein the fabricated of a biodegradable material (**col.4 lines 45-55**).

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 3 and 14 refer to “barbs” which seem to lack antecedent basis.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “barb” of claims 3 and 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

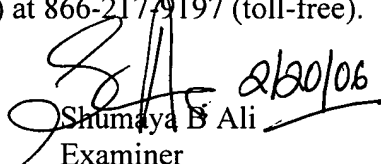
Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

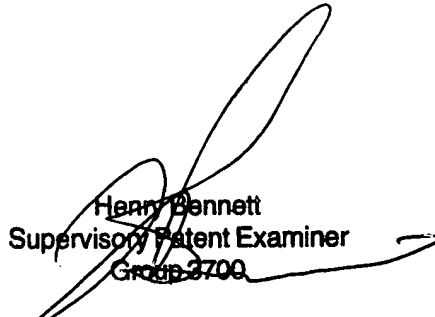
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

Art Unit: 3743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shumaya B. Ali
Examiner
Art Unit 3743


Henry Bennett
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